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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

COUNTS, GARY W

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/937,730	Applicant(s) TAKAHASHI ET AL.	
	Examiner GARY W. COUNTS	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 12, 27, 31, 41, 45, 49, 53 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 12, 27, 31, 41, 45, 49, 53 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Applicant's response filed 05/21/09 is acknowledged and has been entered. Currently, claims 5, 12, 27, 31, 41, 45, 49, 53 and 60 are pending and under examination.

Withdrawn Rejections

1. All rejections of claims not reiterated herein, have been withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 5, 12, 27, 31, 41, 45, 53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 6,284,194) in view of Shigehiro (JP11258239) (English computer translation provided).

Chu discloses an analytical device and method of making the device. Chu teaches that the device comprises a porous reaction membrane and at least one receptor immobilized in a limited region (col 1, lines 40-50) (reaction layer and reactive components). Chu teaches applying a surfactant (surface active agent) to the reaction membrane and allowing to dry (col 1, lines 55-67). Chu teaches that drying can be performed by air drying at room temperature or by warm air with good ventilation (col 9, lines 30-43). The surfactant can be a non-ionic surface active agent (col 8). Chu teaches that all (entire) or most (part) of the surface (col 5, lines 27-32, col 9) is exposed to the surfactant.

Chu differs from the instant invention in failing to teach that the surface active agent comprises a surface active agent having sugar in a hydrophilic part.

Shigehiro discloses immunoassays and teaches the addition of a non-ionic surface active agent having a disaccharide chain at a hydrophilic part to a reagent for the immunoassay (abstract) (para 0003—0008). Shigehiro teaches that the surface active agent is added to an immobilized receptor (para 0004, 0005). According to Shieghiro, the addition of this surface active agent provides for improved assay sensitivity and also provides for increasing only a specific reaction (e.g. abstract, para. 0006).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate surface active agents such as taught by Shigehiro into the analytical device and method of Chu because Chu specifically taught that non-ionic surfactants can be used and Shigehiro taught that the addition of surface active agents having a disaccharide chain at a hydrophilic part provides for improved sensitivity and increased specific reactions in assay applications.

With respect to claims 41 and 45, Chu teaches that drying can be performed by warm air in good ventilation. Therefore, Chu teaches drying by moving air (wind) and thus Chu teaches wind drying as recited in claims 41 and 45.

6. Claims 5, 12, 27, 31, 41, 45, 53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jobling et al (US 6,130,100) in view of Shigehiro (JP11258239) (English computer translation provided).

Jobling et al disclose test strips and a process of manufacturing test strips (abstract and col 2, lines 31-67). Jobling et al disclose that the strip comprises a porous material which comprises a test zone (reactive layer) having immobilized specific binding reagents (reactive components) (col 2, lines 31-67 and col 3, lines 21-26). Jobling et al discloses that a solution comprising Tween 20 (surfactant, surface active agent) is applied to the porous strip and dried (col 6, lines 1-29). The drying step is performed by air drying. (col 6, lines 27-29). Jobling et al also teaches that the solution migrates from one end of the strip to the other end (col 6 and Figures 1-3b). Therefore, Jobling teaches that the entire reactive layer is impregnated with the surface active agent.

Shigehiro discloses immunoassays and teaches the addition of a non-ionic surface active agent having a disaccharide chain at a hydrophilic part to a reagent for the immunoassay (abstract) (para 0003—0008). Shigehiro teaches that the surface active agent is added to an immobilized receptor (para 0004, 0005). Shigehiro teaches that the addition of this surface active agent provides for improved assay sensitivity and also provides for increasing only a specific reaction (e.g. abstract, para. 0006)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate surface active agents such as taught by Shigehiro into the method of Jobling et al because Jobling et al specifically taught that surfactants are added and Shigehiro taught that the addition of surface active agents having a disaccharide chain at a hydrophilic part provides for improved sensitivity and increased specific reactions in assay applications.

7. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu or Jobling et al in view of Shigehiro as applied to claims 5, 12 , 27, 31, 41, 45, 53 and 60 and further in view of Iwata et al (US 5,912,139).

See above for teachings of Chu, Jobling et al and Shigehiro.

Chu, Jobling et al and Shigehiro differ from the instant invention in failing to teach the reactive layer is dried by freeze drying.

Iwata et al disclose producing a test strip by impregnating a carrier with a solution comprising components. Iwata et al disclose that the impregnated carrier is then dried by freeze drying (col 6, lines 48-59). The components can be surfactants (col 6, lines 3-14 and col 10, lines 10-22). Freeze drying thoroughly removes water from the carrier (col 6, line 53). Iwata et al disclose that this provides for a test strip having a high sensitivity and high accuracy measurement with excellent storage stability (abstract & col 2, lines 22-43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate freeze drying as taught by Iwata et al into the modified method of Chu because Iwata et al taught that freeze drying thoroughly removes water from the carrier and Iwata et al also taught that this provides for a test strip which provides high sensitivity and high accuracy measurement and excellent storage stability.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate freeze drying as taught by Iwata et al into the

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modified method of Jobling et al because Iwata et al taught that freeze drying thoroughly removes water from the carrier and Iwata et al also taught that this provides for a test strip which provides high sensitivity and high accuracy measurement and excellent storage stability.

Response to Arguments

8. Applicant's arguments filed 05/21/09 have been fully considered but they are not persuasive.

Applicant argues that the primary effect of Shigehiro is that the sensitivity of the reaction itself can be improved by adding a nonionic surface active agent having a disaccharide chain at a hydrophilic part to a liquid phase reaction system and that Shigehiro relates to the homogeneous assay field. Applicant states that in contrast, Applicants' invention relates to a heterogeneous assay, which is quite distinct from the homogeneous assay of Shigehiro. Applicant directs the Examiners attention to page 7, lines 5-12 of the original specification.

Applicant's arguments are not persuasive because they are not on point. The claimed invention is directed to a product and a method of making the product, and not directed to assay methods and applications of the chromatography medium.

Applicant further argues that improving the sensitivity in the homogeneous assay field, which does not require binding/free separation, cannot directly correlate to improving the sensitivity in the heterogeneous assay field, which does perform binding/free separation. Applicant states that though Shigehiro substantiates and

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teaches that the sensitivity is improved by using the above-mentioned surface active agents with showing various reaction examples, each of the examples relate to the homogeneous assay. Applicant then describes the principle of the homogenous assay and states that in a homogenous assay where the latex particles disclosed in Shigehiro are used as labeled substance, even if no antigen-antibody reaction occurs, the same number of latex particles exist in the reaction system and where an antigen-antibody reaction does occur, the same numbers of latex particles still exist. Applicant states that in this case, though the signal change caused by agglutination reaction can be captured, a signal is generated due to that the latex particles which do not practically relate to the agglutination reaction coexist, thereby generating a so-called noise. Applicant then states that on the contrary, if the heterogeneous assay using the latex particles is assumed, the latex particles which are not involved in an antigen-antibody react are eliminated by binding/free separation. Thus, the signals which are caused only by the bound latex particles in the antigen-antibody reaction could be finally detected, and the signals caused by unreacted latex particles (which would become noise) are substantially eliminated.

These arguments are not found persuasive because the arguments are not on point because the Examiner is not relying on the use of latex particles in any assay format but rather is relying upon the primary references of Chu and Jobling as teaching applying surface active agents to surfaces comprising reactive layers and relying upon the secondary reference of Shigehiro for teaching that it is known to use an obvious

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variant of a surface active agent comprising a sugar in a hydrophilic part of the agent in immunoassays.

Applicant argues that the teaching of Shigehiro, which describes the reacting sensitivity enhancement in a homogeneous assay, cannot provide motivation for a substitution in the heterogeneous assay field and that one of ordinary skill in the art would not have looked to Shigehiro to remedy the deficiencies of Chu and Jobling et al.

This is not found persuasive because it appears that Applicant is arguing that Shigehiro is non-analogous art. This is not found persuasive because Chu et al specifically teaches that non-ionic surfactants can be exposed to the surface of a chromatography medium and one of ordinary skill in the art would be motivated to look into the field of immunoassays for obvious variants of non-ionic surfactants used in immunoassays. Further, the teachings of Shigehiro showing that surface active agents comprising a sugar in a hydrophilic part of the surface active agent provides for the suppression of non-specific reactions and increases specific reactions and regardless if an assay is homogeneous or heterogeneous one of ordinary skill in the art would be motivated to provide increased specific reactions and the suppression of non-specific reactions. Therefore, for the reasons stated above one of ordinary skill in the art would be motivated to incorporate a surface active agent such as taught by Shigehiro into the methods and devices of Chu et al or Jobling et al because one would look for obvious variations and advantages of the surface active agents for the purposes of Chu et al and Jobling et al with the motivation to provide for increased specific reactions and the suppression of non-specific reactions.

Conclusion

9. No claims are allowed.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/

Examiner, Art Unit 1641

/GAILENE R. GABEL/

Primary Examiner, Art Unit 1641

8/12/09